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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,216	02/04/2002	Gregory P. Pogue	43276	3510

7590 05/27/2005

John C. Robbins
Intellectual Property Department
Large Scale Biology Corporation
3333 Vaca Valley Parkway, Suite 1000
Vacaville, CA 95688

EXAMINER

FOLEY, SHANON A

ART UNIT PAPER NUMBER

1648

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/061,216

Applicant(s)

POGUE ET AL.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70 and 79-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70 and 79-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

In the amendment submitted March 15, 2005, applicant amended claims 70, 79, 82-84 and added new claim 88. Claims 70 and 79-88 are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 82-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

Applicant has amended these claims by deleting "step" to remedy the lack of antecedent basis. However, this word was not an issue and should not have been deleted. As stated previously, the specific recitations quoted in the last Office action are not found in the claims from which claims 82-84 depend. However, the limitations following "said" in claims 82-84 are found in claim 79. In order to render the instant rejection moot, claims 82-84 should be amended to depend from claim 79. Such an amendment would not only obviate the instant rejection, but it would also be consistent with the treatment of dependencies in claims 85-88.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 70 and 79-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garger et al. (US 6,033,895), (US 6,037,456), (US 6,303,779 B1) or (US 6,740,740 B2), each in the alternative, Koprowski et al. (US 6,042,832) and Francon et al. (US 5,075,110).

Since claim 88 does not present a limitation that is not rendered prima facie obvious by the references previously cited, the rejections of record also apply to this claim.

Applicant asserts that the rejection is defective for at least five reasons:

1) Applicant asserts that the combination of references do not teach or suggest a solvent extraction after a PEG/salt precipitation, as instantly recited.

Applicant's arguments and a review of the references have been fully considered, but are found unpersuasive because Gooding et al. (cited by Garger et al. in column 3, lines 23-32 of '895) teach purifying plant viruses by adding n-butanol, followed by treatment of the supernatant with PEG. Gooding et al. further teach that the "virus can be further purified by another cycle of resuspension" (i.e. addition of n-butanol), "centrifugation and PEG-precipitation", see lines 32-33. Therefore, contrary to applicant's assertion, the prior art does teach PEG treatment following treatment with n-butanol. The instant method claimed "comprises" steps that does not exclude additional steps taught in the prior art.

2) Applicant argues that the Koprowski et al. use PEG/NaCl to treat a different liquid from the liquid of the invention because Koprowski et al. use physical means of extraction rather than chemical. Applicant argues that one would not be motivated to add a purification technique that is used on a different material.

Applicant's arguments and a review of the references have been fully considered, but are found unpersuasive. It is known in the prior art that PEG precipitates virus, see column 3, lines

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29-33 of Garger et al. ('832). Koprowski et al. also use PEG to precipitate virus, see column 12, lines 60-63. In the instant case, the chemical steps recited previous to the addition of the PEG solution are performed to remove plant tissue and debris to arrive at a suspension of virus particles. In the method of Koprowski et al., the physical steps taught also remove plant material and debris to obtain a suspension of virus particles that are then precipitated with a PEG solution. Therefore, although different routes obtain virus suspensions, a solution comprising PEG precipitates virus in either case.

3) Applicant contrasts the simple homogenized plant material of Gooding et al. and the instant chemically treated homogenized plant material treated by a solvent to extract virus. Applicant argues that there is no motivation to use a purification technique that is used on a different material.

Applicant's arguments have been fully considered, but are found unpersuasive. Garger et al. teach that the use of solvents, such as n-butanol and chloroform, eliminate host-related material, see column 3, lines 47-51. N-butanol removes cellular material to obtain a virus suspension, which is precipitated with PEG and further purified by another treatment with n-butanol and re-precipitated with PEG, see column 3, lines 23-33. In the instant case, cellular material is also removed by a chemical treatment before precipitating the virus with PEG, followed by removing any residual debris by further treatment with butanol. In both cases, solvents are used for the same purpose of eliminating extraneous cellular debris.

4) Applicant points out that the salt concentration of used in the present invention is 12-fold higher than that used by Koprowski et al. and affects the solubility of certain materials.

The difference in salt concentrations has been fully considered. However, MPEP § 2144.05 states that “Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)”. In the instant case, applicant has not identified an unexpected result stemming from the salt concentration recited and none is readily apparent. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to optimize the salt concentration to maximize virus precipitation, absent unexpected results to the contrary.

5) Applicant concludes that Garger et al. discourage the use of organic solvents in column 3, lines 52-53 and column 9, lines 56+.

A review of the references has been fully considered. While it is agreed that Garger et al. discuss the difficulties of using solvents for large-scale virus production in column 9, Garger et al. never teach not to use solvents. Garger et al. actually identify the requirements necessary to circumvent the problems associated with large-scale solvent use, see column 9, lines 60-65. From the teachings in the reference, it is apparent that while solvent use in large-scale methods is cumbersome, there is no indication that solvents do not eliminate host cell materials (as they do in small-scale preparations). Garger et al. actually state that using solvents in virus isolation procedures are “useful and effective for small-scale virus purification...”, see column 3, lines 51-52. Since the instant claims do not specify whether the virus is isolated on a small or large scale,

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it is determined that using a solvent for the virus purification method instantly claimed is “useful and effective”, as taught by Garger et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-Th 6:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Shanon Foley
Primary Examiner
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